#7 CP 8/8/02

Practitioner's Docket No. 2028US *PATENT*

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Date: August 1, 2002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Gorlach et al.
Application No.: 09/770,423
Filed: 26 January 2001
For: Expressed Sequences of Arabidopsis Thaliana

Group No.: 1634
Examiner: S. Sakelaris

Assistant Commissioner for Patents
Washington, D.C. 20231

RESPONSE TO RESTRICTION REQUIREMENT

Dear Sir:

This is a restriction election in response to the Office Action dated 04 June 2002 requiring restriction of the claims. Also enclosed is a Petition for Extension of Time and a Small Entity Statement.

I. Restriction Election

The Examiner has required restriction between Group I (Claims 1-3, 5-24, and 26), Group II (Claims 4 and 27), and Group III (Claim 25). The Examiner has also required a restriction to elect a single amino acid or nucleic acid sequence from the multiple SEQ ID numbers recited within each group.

Applicants hereby provisionally elect, with traverse, to prosecute Group I (Claims 1-3, 5-24, and 46) drawn to polynucleotides, vectors, host cells, and transgenic plants. Applicants further elect to prosecute SEQ ID NO:1 within the elected restriction Group I. Applicants reserve the right to file divisional applications or take other appropriate measures deemed necessary to protect the inventions in the remaining claims.

II. Restriction to a single nucleotide or polypeptide sequence is traversed.

The Examiner's restriction requirement limiting all claimed nucleotide and polypeptide sequences to one sequence per invention is respectfully traversed. The administrative rule 37 C.F.R. § 1.141(a), promulgated by the PTO, allows more than one species of an invention to be claimed as long as it does not exceed a "reasonable" number.

In interpreting the statutory term "reasonable," the PTO has previously given public notice in its *Official Gazette* that allowing up to 10 nucleotide sequences in one application was sufficiently "reasonable" without causing an undue search burden on an examiner. See 1192 O.G. 68, (Nov. 19, 1996) (Commissioner of Patents and Trademarks interpreting the PTO statutory rule, 37 C.F.R. § 1.141(a), to allow up to 10 nucleotide sequences per application in the interest of promoting the biotechnology industry).

Prior to the adoption of the current form of 37 C.F.R. § 1.141(a) in 1978, § 1.141 limited the number of independent and distinct species allowable per application to 5. See 52 FR 20038, (Apr. 28, 1987), Donald J. Quigg, Assistant Secretary and Commissioner of Patents and Trademarks, FR Doc. 87-11977. Therefore, the (recent) change in the interpretation of "reasonable" from 5 sequences to 10 sequences is consistent with an intention to increase the number of allowable independent sequences per application, as opposed to a decrease in the number to only one.

Furthermore, no other PTO publication, PTO web site posting, or other PTO published rule has interpreted the statutory term "reasonable" in § 1.141 to mean only one nucleotide sequence is allowable per application. In contrast, existing public notices in the MPEP, the PTO *Official Gazette*, and in notices posted to the PTO website, have interpreted the term "reasonable" to *include up to 10 nucleotide sequences per applicatio*n. See http://www.uspto.gov/web/ offices/com/speeches/96-21.txt. Therefore, Applicants respectfully submit that for purposes of public notice by an administrative agency, the phrase "reasonable number of species" should be interpreted to include more than one distinct nucleotide sequence per application.

In fact, the Federal Circuit has commentated that although courts are not mandated to follow the language of the MPEP itself, courts are entitled to take "judicial

notice" of the MPEP as far as it is an official interpretation of statutes or regulations with which it is not in conflict. *See Litton Systems, Inc. v. Whirlpool Corp.*, 221 U.S.P.Q. 97, 107 (Fed. Cir. 1984). It is likely, therefore, that a reviewing court would take "judicial notice" of the fact the MPEP § 803.04 (8th ed. rev. 2001) recites that a "reasonable" number of species can include up to 10 nucleotide sequences.

In addition, as evidence of PTO practice concerning multiple sequence listings in one application, Applicants cite the following patents issued with greater than one sequence listing. See *e.g.* U.S. Patent Nos. 6,333,152; 6,013,508; and 5,928,871. In each instance cited *supra* by Applicants, the multiple sequences listed were not always derived from the same functional enzymatic family. Applicants submit that the present invention should not be restricted to a single nucleotide sequence, as evidence of PTO practice shows that greater than one distinct nucleotide sequence is allowable.

If the Examiner agrees with Applicants' argument for prosecution of ten sequences as one invention in the present application, Applicants elect prosecution of SEQ ID NOS:1-10.

III. Restriction of the claims into 3 separate inventions is traversed.

The requirement to restrict Applicants' claims into three separate inventions is respectfully traversed. The Examiner has required restriction between Group I (Claims 1-3, 5-24, and 26), Group II (Claims 4 and 27), and Group III (Claim 25). Applicants respectfully traverse the restriction and propose that the application be restricted into two inventions, wherein Groups I and II are recombined to consist of Claims 1-24, 26, and 27.

It is stated in the MPEP that where claimed inventions are related and are shown to be distinct, the examiner, in order to establish reasons for insisting upon restriction, must show by appropriate explanation one of the following: 1) separate classification 2) separate status in the art when classifiable together 3) or a different field of search. See § 803.04 (8th ed. rev. 2001). Applicants respectfully submit that in the present case evidence has not been provided to necessitate the restriction of the nucleotides of Group I and the polypeptides of Group II into independent and distinct inventions.

Applicants respectfully assert that the recombination of Claims 1-24, 26, and 27 (Groups I and II) is logical and legally proper because nucleic acids and polypeptides are

commonly understood in the art to be not only interrelated, but to be critically interdependent upon each other. A nucleotide sequence encodes a distinct polypeptide sequence. The databases containing nucleotide and polypeptide sequences are inter-linked. From the fields of genomics to proteomics to transgenic organisms, nucleic acids and polypeptides are commonly referred to simultaneously in the same publication. Therefore, Applicants assert that it is not possible to provide an appropriate explanation as to why nucleotides and their encoded polypeptides require one of separate classification, separate status in the art when classifiable together, or a different field of search.

Furthermore, as evidence of PTO practice, Applicants' cite the following recently issued patents that have claims directed to both nucleic acids and polypeptides. See *e.g.* U.S. Patent Nos. 6,348,582 (*Prokaryotic polynucleotides polypeptides and their uses*); 6,352,830 (*NF-AT polypeptides and polynucleotides and screening methods for immunosuppressive agents*); 6,340,584 (*Isolated human kinase proteins, nucleic acid molecules encoding human kinase proteins, and uses thereof*); 6,344,353 (*Isolated human protease proteins, nucleic acid molecules encoding human protease proteins, and uses thereof*); 6,338,844 (*Genomic nucleic acids, cDNA and mRNA which code for polypeptides with IL-16 activity, processes for the production thereof and their use*); 6,352,843; 6,313,375; 6,307,125; 6,255,561; 6,211,437; and 6,303,332.

In light of the foregoing, Applicants respectfully request that the claimed invention be regrouped such that Group I and Group II are recombined into Claims 1-24, 26, and 27.

Applicants submit that the case is in condition for prosecution and such action is respectfully requested. However, if any issue remains unresolved, Applicants' agent welcomes the opportunity for a telephone interview to expedite allowance and issue.

Respectfully submitted,

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